

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters
Products Liability Litigation

) MD-15-02641-PHX-DGC

) Phoenix, Arizona
) April 13, 2018
)

Doris Jones, an individual,

)
)
) Plaintiff,

) CV-16-00782-PHX-DGC

)
)
) v.
)

C.R. Bard, Inc., a New Jersey
corporation; and Bard Peripheral
Vascular, Inc., an Arizona
corporation,

)
)
)
) Defendants.
)
)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

PRETRIAL CONFERENCE

Official Court Reporter:
Patricia Lyons, RMR, CRR
Sandra Day O'Connor U.S. Courthouse, Ste. 312
401 West Washington Street, SPC 41
Phoenix, Arizona 85003-2150
(602) 322-7257

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

A P P E A R A N C E S

For Plaintiff:

Gallagher & Kennedy
By: **MARK S. O'CONNOR**, ESQ.
By: **PAUL L. STOLLER**, ESQ.
By: **SHANNON L. CLARK**, ESQ.
By: **C. LINCOLN COMBS**, ESQ.
2575 East Camelback Road, Suite 1100
Phoenix, AZ 85016

For Defendants:

Nelson Mullins Riley & Scarborough
By: **ELIZABETH C. HELM**, ESQ.
By: **JAMES F. ROGERS**, ESQ.
By: **MATTHEW B. LERNER**, ESQ.
201 17th Street NW, Suite 1700
Atlanta, GA 30363

Snell & Wilmer
By: **JAMES R. CONDO**, ESQ.
By: **AMANDA C. SHERIDAN**, ESQ.
400 East Van Buren
Phoenix, AZ 85004

P R O C E E D I N G S

THE COURTROOM DEPUTY: MDL 2015-2641, Bard IVC
Filters Products Liability Litigation on for hearing in
regards to the Jones trial.

Will the parties please announce.

MR. O'CONNOR: Good morning, Your Honor. Mark
O'Connor, Paul Stoller, Shannon Clark, and Lincoln Combs on
behalf of the plaintiffs.

THE COURT: Morning.

MR. ROGERS: Morning, Your Honor. Jim Rogers,
Matthew Lerner, and Kate Helm from Nelson Mullins on behalf of
the defendants. Also, we have Jim Condo and Amanda Sheridan
also on behalf of defendants.

THE COURT: Morning.

All right. Let's talk through the issues that you've
identified in your brief, briefs, for the today's hearing, and
then there's some other matters we ought to cover.

The first issue, starting with defendants' brief, is
the assertion that evidence regarding Recovery filter
complications and development should be excluded. I've read
what the defendants have filed. I've read the brief that the
plaintiffs filed last night.

Why don't we get defendants' thoughts on that issue
in light of what's been said so far.

10:02:05 1 MR. LERNER: Your Honor, if it's okay I could
2 probably address Motion in Limine Number 1 and 2 together.

3 THE COURT: Well, I'd like to talk about cephalad
4 migration separately. But if you want to talk about both,
10:02:19 5 that's fine, but I do want to have a specific discussion about
6 cephalad migration.

7 MR. LERNER: For Motion in Limine Number 1, I think
8 our focus is on cephalad migration. As we said in our briefs,
9 the Eclipse filter here is Bard's fourth generation filter.
10:02:33 10 It's electropolished. It's five years after the Recovery
11 filter was off the market. There's no allegations, or I'm not
12 aware of any complaints where there's an Eclipse filter that
13 migrated to the heart and caused death.

14 In this case, in Ms. Jones' case, it was a case of
10:02:52 15 fracture with a strut that went to the lungs.

16 So there's a lot of time spent in the Booker case, I
17 just did a search of the transcripts from the Booker case and
18 there's over 200 entries of the word "death" in the trial
19 transcripts. So that means on average 20 times a day the jury
10:03:07 20 was hearing things about cephalad migration or death, and
21 things that are really not relevant to this case.

22 I think it's confusing as well to the jury in this
23 case about an Eclipse filter that happened -- that was
24 developed long after Recovery filter, that they're going to be
10:03:23 25 discussing migration to the heart of a filter that's not at

10:03:27 1 issue here. I think it's confusing and even if it had
2 marginal relevance, it just inflames the jury about issues
3 that are not really relevant to the Eclipse filter that is at
4 issue here.

10:03:39 5 The other thing, as part of that there's a lot of
6 testimony talking about the testing for migration and
7 50-millimeters of mercury and what that meant, and whether the
8 Recovery filter passed that specification or not. There's no
9 issue here with the Eclipse filter that it passes migration
10:03:55 10 specifications. There's not a dispute here. So I think it's
11 very confusing to the jury to be talking about that sort of
12 testing and deaths when that is simply not an issue in this
13 case.

14 THE COURT: Well, I take it that you are arguing,
10:04:13 15 Mr. Lerner, in addition to your argument that the deaths
16 should be set aside, at least your brief seemed to suggest you
17 don't think any evidence should come in about the Recovery or
18 its development or about its testing or about the complication
19 rates that were experienced.

10:04:30 20 MR. LERNER: I think the existence of the Recovery
21 filter, that it was in the line of filters, that background,
22 sure. I also think that the complication related to the
23 Recovery filter are not relevant in this case. I'm even more
24 kind of sensitive to and focused on the cephalad migration as
10:04:51 25 a bigger issue and that being a particular thing that should

10:04:55 1 be excluded because I think it's just confusing and it's
2 inflammatory and unduly prejudicial and confusing.

3 So although I think -- I don't think that the testing
4 rates of the Recovery filter is relevant, I don't think the
10:05:07 5 other complications relating to Recovery -- because the
6 Eclipse filter, if you look at the clinical experience, it
7 eliminated the cranial cephalad migration, fracture resistance
8 was improved, and the predicate device for the Eclipse is the
9 G2 Express.

10:05:23 10 So we talked a lot in the Booker case about
11 substantial equivalence and the representations were we made
12 the representations to the FDA that the G2 was substantially
13 equivalent to the Recovery.

14 Well, here we have Bard's fourth generation. You
10:05:38 15 have the Recovery, the G2, the G2 Express, and now the
16 Eclipse. It's very attenuated from the circumstances of this
17 case.

18 That's -- those are some of reasons why we think that
19 that that should be excluded.

10:05:50 20 THE COURT: Okay. Thanks.

21 Plaintiff's counsel.

22 MR. STOLLER: Morning, Your Honor. Paul Stoller for
23 plaintiffs.

24 I will start with the last issue first and work my
10:06:10 25 way back to the cephalad migration issue.

10:06:13 1 The question here and the issue that the defendants
2 framed in their -- I'm going to put air quotes around the term
3 "renewed" motion for -- to eliminate or exclude the Recovery
4 evidence is premised on a false premise that the Eclipse is a
10:06:30 5 different device from the G2.

6 You've heard this issue and this argument as relates
7 to the G2 and why the Recovery evidence is relevant to the G2.
8 It's relevant to the Eclipse for the exact same reason. And
9 it essentially is that because while there is time between the
10:06:49 10 G2 coming to the market and the Eclipse coming to the market,
11 they're the same device and Bard treats them as the same
12 device. They trained their sales and reps -- sales reps and
13 employees they're the same device. And they are the same
14 device.

10:07:03 15 Only difference between G2 and the Eclipse is they
16 added a hook to the top, which is the G2 Express, which has
17 nothing to do with any of the design and complication issues
18 here, and then they colored it blue and they electropolished
19 it.

10:07:20 20 Now, they would make today some claim that the
21 electropolishing is some significant difference. But at the
22 time they did it they didn't believe it had anything to do
23 with a change to the design that was focused at or implemented
24 in order to correct any of the complications that are at issue
10:07:39 25 with the G2 or with the Recovery.

10:07:40 1 In fact, their vice president of research and
2 development was very clear about that. Effectively they
3 didn't have any reason to believe it was going to do anything,
4 this was just to conform with the industry practices with
10:07:51 5 respect to Nitinol.

6 Electropolishing is nothing more than -- the word
7 "sanding" is probably too abrasive a term under the
8 circumstances, but it's removing microimperfections. They had
9 no reason to believe that that changed anything about the
10:08:08 10 device. It was not the reason for doing it.

11 Effectively it's like taking the Ford Pinto, painting
12 it green, polishing it, and calling it a Stallion and saying
13 it's a different design.

14 It's not.

10:08:20 15 The Eclipse is, in fact, dimensionally and
16 proportionally, the width and strength of the various arms,
17 legs, hooks, identical to the G2. So let me start with that
18 premise.

19 When you -- then the question becomes, and, again,
10:08:34 20 you've heard this issue before, how is the Recovery relevant
21 to the G2 and thus to the Eclipse as well?

22 The story here, Your Honor, is one of -- let's start
23 with our claims. Our claims on design defect, both in strict
24 liability and negligence, are that Bard's actions were not
10:08:52 25 reasonable in developing the -- designing and developing the

10:08:56 1 filter, and that goes all the way back to the very beginning
2 the Recovery.

3 Why? Two reasons.

4 One is, based on what they knew about the Recovery,
10:09:03 5 that device never should have been on the market. Their point
6 of failure starts from the get-go.

7 If the Recovery's never on the market because they
8 didn't do the things they were supposed to do there, including
9 appropriate testing, they never did a clinical trial, the
10:09:17 10 design issues that they were aware of before they even took
11 that device to market, takes that -- not only that device off
12 the market, but all the subsequent devices off the market.

13 But the other thing in terms of the design and
14 development story is that in terms of the reasonableness of
10:09:32 15 its activities, what happened with the Recovery is highly
16 relevant to the G2 and the subsequent Eclipse because every
17 point along the way Bard, first, did things improperly in
18 terms of the design and then when they moved from Recovery to
19 the G2, it was, one, an immediate reaction to what happened
10:09:57 20 with the Recovery, so we'll talk about this a little bit more
21 when we talk about the cephalad migrations, but it was in
22 reaction to what happened with the Recovery, but improperly
23 so. Because they didn't do the right testing.

24 So if you go back to the beginning and you start with
10:10:11 25 Dr. Asch, they have complications in that study. Unexpected

10:10:15 1 complications. They tell Dr. Asch and they have internal
2 documents that say things like if we have one more migration,
3 we're going to stop it and redesign it. And they do have more
4 migrations. But they don't. They don't stop. They don't
10:10:27 5 redesign it.

6 You get to the special design review committee that
7 convenes in December of 2003, weeks before they take it to
8 full market release. They list a number of questions. What's
9 our support for this? What's our support for the 50
10:10:42 10 millimeters mercury migration standard? What's our support
11 for -- how do we compare to these other things? Before we get
12 to market, here's another flashing red light to stop. And
13 they blow past that without doing anything at all.

14 And there's these consistent signs along the way that
10:10:59 15 they should have stopped. They didn't do root cause analyses
16 to figure out why the filter was migrating towards the heart
17 and causing deaths. They knew it was a problem, but they
18 never knew why.

19 And so when you get to the design of the G2, while
10:11:15 20 it's reactive, it's without knowledge.

21 And you'll hear, and you heard from the stand, from
22 Dr. McMeeking in the Booker trial, say they did not test the
23 Recovery appropriately, they did not determine in that time
24 period in 2004 and early 2005 the root cause for why these
10:11:33 25 failures were happening, and so when they went to design the

10:11:36 1 G2, the G2 design is a direct result of that. They thought,
2 hey, we're moving towards the heart. So how do we do that?
3 We'll make it wider. Substantially wider. That was a direct
4 result or -- direct result of those cephalad migrations and
10:11:52 5 why they changed it, but they didn't know what that result --
6 they didn't understand -- sorry.

7 They did not understand why it was moving up, and so
8 their solution was we'll just make it wider and that will fix
9 it. What you heard from Dr. McMeeking is that making it wider
10:12:07 10 causes a whole other set of issues that arise in the G2, which
11 is that it forces -- because he talked about it as spring,
12 right? He said that makes this one a spring that is trying to
13 fit in a hole that's this big when it's this big, and that
14 forces it to tilt which forces it to perforate which causes
10:12:26 15 fractures.

16 So all these things, these design problems that exist
17 in the G2 and also in the Eclipse, are a direct result of
18 Bard's failure to properly test, failure to do root cause
19 analyses, and design reactively without determining -- again,
10:12:42 20 without doing proper tests on the G2 or doing clinical study
21 on the G2 that would have alerted them that we're going to
22 have the big problems that come with the G2.

23 Does the G2, does the Eclipse migrate caudally? I'm
24 never -- we can't say never, but certainly -- and it certainly
10:13:01 25 doesn't at the rate of the Recovery filter.

10:13:03 1 But it does -- but all of the things, all of the
2 design problems with the G2 tie back to all its failures in
3 terms of what it did with the Recovery and start back right
4 from the very beginning with the Asch study.

10:13:18 5 And they tie, candidly, very directly to this issue
6 of cephalad migration because if they don't have cephalad
7 migration or if they do a proper root cause -- again, I keep
8 saying "they." It's Bard. If Bard does a proper root cause
9 analysis or if they don't have cephalad migration with the
10:13:37 10 Recovery, you do not have the same design of the G2 and thus
11 the Eclipse.

12 That whole history is entirely relevant to the claim
13 for negligence, for their failure to act reasonably in their
14 testing and design. It's relevant to the claims on the design
10:13:51 15 defect itself in terms of what did they do? Was it a
16 reasonable process they undertook in designing this? Did the
17 risks outweigh the benefits? And did they understand it?
18 Because they never did.

19 This was, as you know, from plaintiff's perspective,
10:14:03 20 and you had a jury here not that long ago, found punitive
21 damages. This was a company that put a product out on the
22 market without having adequately tested it, both at the
23 Recovery stage and at the G2 stage. Without having adequately
24 tested it clinically, without having adequately tested it in
10:14:20 25 terms of the lab tests and bench tests they did, and that

1 carries through. And had they -- they kept things on the
2 market in order to preserve their position rather than
3 stopping at the very beginning and saying we need to do an
4 appropriate full clinical test to see whether this works or
5 not before we use the human patient population as a guinea pig
6 experiment.

7 So they're intricately related.

8 They're tied both to our claims, our substantive
9 claims, this evidence about both, about the Recovery itself
10 and its design and development and the cephalad migration to
11 the substance of our claims and how we're going to prove to
12 the next jury that this is a defective design, that they were
13 negligent in the design of the device at issue before this
14 jury, and it's relevant to our claim for punitive damages.

15 THE COURT: Let me ask you a question on cephalad
16 migration.

17 The defendants have asserted there is no instance of
18 cephalad migration resulting in death after the Recovery
19 filter. Do you agree with that?

20 MR. STOLLER: I can't -- let me -- I can't contest
21 that. I don't know the -- I do not know that that is not
22 true. So I don't know that it is true, but I can't contest
23 it.

24 THE COURT: You don't know of any instances --

25 MR. STOLLER: I do not.

10:15:38 1 THE COURT: -- of cephalad migration causing death
2 after the Recovery?

3 MR. STOLLER: I do not, Your Honor.

4 THE COURT: And do you also agree there is very
10:15:47 5 little, if any, evidence of cephalad migration at all after
6 the Recovery?

7 MR. STOLLER: All things are relative. They would
8 argue there's very little evidence of any migration, so it's a
9 relative term. I will say there is not a lot of cephalad
10:16:02 10 migration. It is, again, tying back to a direct result of why
11 they designed the G2 the way they did.

12 If they had done a root cause analysis and said it's
13 migrating caudally -- excuse me, cranially for this reason and
14 we need to determine what are the appropriate diameters of it
10:16:19 15 and done some research and study and those sort of things and
16 made a determination as to those issues and designed based on
17 that, we might be in a different world today.

18 The problem is and the reality is they suffered death
19 after death after death because they had not properly designed
10:16:34 20 the Recovery in the first instance with respect to -- with
21 respect to a number of issues, but particularly as we're
22 talking about here, with respect to its likelihood to migrate
23 to the heart.

24 In reaction to that, they then just said, well, we're
10:16:49 25 just going to make it much wider. And it is significant in

10:16:52 1 understanding the reasonableness of that decision, of why did
2 they go from something that was -- I don't have the dimensions
3 in front of me, but something that was around an order of 28
4 to 32 millimeters in width to something that was 40
10:17:10 5 millimeters, plus or minus, without testing anything. It was
6 an extreme reaction, Your Honor, to what had happened.

7 Again, the fact of the cephalad migrations is
8 relevant. The fact of the deaths is relevant, too, for this
9 reason, and I don't think we overplayed our hand in Booker and
10:17:24 10 we're not going to overplay our hand in Jones on this issue,
11 but it is relevant to what they did. They faced multiple
12 deaths as a result of that. And instead of doing a proper
13 root cause analysis and saying why is this happening, why are
14 these things moving, they made a conclusory determination
10:17:42 15 that, well, what we'll do is just make this substantially
16 wider. And they didn't test it. They didn't determine what
17 effects that would have in terms of these other failure modes
18 we're talking about.

19 Does it fix -- I'm going to use air quotes again
10:17:56 20 around the word "fix." Does it fix caudal migration? By in
21 large, yes, it does. But it is the very reason that the G2,
22 and thus the Eclipse, suffer all of the cascade of problems
23 they suffer.

24 And, again, Dr. McMeeking testified to this in Booker
10:18:15 25 and will testify to it again in Jones, that that design

10:18:19 1 decision, one that was not based on any determination of root
2 cause, that was not based on any testing at all, is the reason
3 for the problems with this device. And, as a matter of fact,
4 the reason they made that change ties directly to these
10:18:31 5 cephalad migrations and directly to the -- and the
6 reasonableness of it -- and you've heard me.

7 THE COURT: You've made that point.

8 But this is the question I want to ask you: I
9 understand your argument that the cephalad migrations, in your
10:18:46 10 view, caused Bard to take a step in the design that was
11 untested and that led to other problems which the plaintiffs
12 have experienced. And so I understand your argument as to why
13 the phenomenon of cephalad migration is relevant in telling
14 the design defect story.

10:19:06 15 I'm having more difficulty understanding why the
16 deaths are relevant. It's the fact of cephalad migration that
17 you say caused them to expand it, and by and large fixed that
18 problem. So the jury, I think -- I think your argument's
19 reasonable, the jury should be able to understand that chain
10:19:25 20 of events. But why do the deaths play a role in that
21 relevancy?

22 MR. STOLLER: Your Honor, the jury's got to decide
23 the reasonableness of their conduct in two places: Both on
24 the substance of our claim on our substantive claim for
10:19:40 25 negligence and reasonableness of their actions is part of what

10:19:42 1 they're going to have to decide. Were these folks reasonable
2 in what they did?

3 And given -- the story, again, it's not just happened
4 here to Ms. Jones, it's the whole story from the get-go.

10:19:54 5 Our contention is that these devices never should
6 have been on the market from the very get-go. They were not
7 reasonable in their actions starting from the Asch study right
8 through the end, and the failure -- again, death after death
9 after death, the weight of the consequences here are important
10 in terms of evaluating the reasonableness of what they did.

11 Was it reasonable for them not to determine a root cause?

12 A jury would weigh it differently. Candidly, I think
13 they would. Is it reasonable for them not to have done
14 anything, or not to have done testing if the caudal

10:20:29 15 migration -- I'm sorry, if the cephalad migrations in the
16 Recovery had been 25 millimeters? What if they'd only been 25
17 millimeters? Well, the jury could assess that and say, you
18 know, not that unreasonable not to have to go and figure out a
19 root cause in that case. Not that unreasonable to not
10:20:49 20 necessarily do a bunch of design testing.

21 It is, in that context understanding -- and, again, I
22 don't think we overplayed our hand in Booker on these things.
23 We didn't parade out death after death after death and spend
24 hours on it. It is part of the story.

10:21:08 25 Is it reasonable when you're having these kind of

1 consequences as a result of your initial design, which we take
2 issue with from the very beginning and should never have been
3 on the market in the first place, that's our case, but is it
4 reasonable even assuming you get past that issue to not
5 take -- not do root cause analyses, not do adequate testing,
6 given the significant problems they cause. It's a big
7 difference between a death and something that moves just a
8 little bit and it will be in the jury's mind in terms of
9 assessing reasonableness.

10 THE COURT: All right. I understand that point.
11 Thank you.

12 Mr. Lerner.

13 MR. LERNER: Again, there is no cephalad migration in
14 this case. Bard should be judged based on the Eclipse filter.

15 Mr. Stoller talked about punitive damages. Bard
16 fixed the issue it was having with the Recovery filter
17 migrating to the heart. That's not an issue here, and I don't
18 think the jury should be making decisions or considerations
19 about whether, for punitive damages, it's a migration to the
20 heart that caused death with the Recovery filter. It just has
21 no relevance to the claims in this case.

22 We should be judged based on the Eclipse filter
23 itself.

24 THE COURT: All right. Thanks.

25 The third issue that was raised in the Bard memo was

10:22:37 1 the FDA warning letter. And the issue that was raised in the
2 defendants' memorandum was the FDA jury instruction.

3 I will tell you my inclination, and you're free to
4 comment on it.

10:22:49 5 I feel that I should approach the Jones trial as an
6 independent trial and I should take the same approach there
7 that I did in Booker. Namely, I'm not going to rule now the
8 FDA warning letter is admissible. I will make that decision
9 as I hear the evidence come in.

10:23:05 10 Well, I'm now speaking about Section 3 of the warning
11 letter, which I think is really the relevant portion.

12 So we'd go into the trial in the same way we did in
13 Booker, without it being mentioned until such point the
14 defendants believe -- the plaintiffs believe it becomes
10:23:19 15 relevant, then I'd be happy to consider it just as I did in
16 Booker.

17 And similarly on the FDA instructions, I continue to
18 be of the view that the jury understood the nature of the
19 510(k) process, but I also understand what plaintiff has
10:23:34 20 argued about the 510(k) issue.

21 My view is we should settle that at jury instructions
22 when we're in the trial, we know what's being argued, and
23 we've got the context of the trial to make that decision.

24 So I'm not inclined to rule today that the FDA jury
10:23:50 25 instruction should be given, but I'm not closing my mind to

10:23:53 1 that. I want to consider that in the context of the trial.

2 That's what I'm inclined to do with those two issues,
3 but I'm happy to hear thoughts on this.

4 Plaintiffs, do you want to comment?

10:24:09 5 MR. O'CONNOR: I think your proposal is much like we
6 did in Booker and that makes sense.

7 Of course we think the FDA warning letter has
8 relevance to a number of issues, and we've raised that. And
9 to mention in that 3(b) section -- I think it's 3(c), Your
10:24:28 10 Honor, seven of those eight complaints were Eclipse.

11 But I think we understand your position and believe
12 that we will eventually be approaching you during trial on
13 this.

14 THE COURT: All right.

10:24:42 15 Defendants.

16 MR. ROGERS: Your Honor, we don't disagree. I think
17 your approach is clearly reasonable. I think all the parties
18 need to see how the evidence comes in and ultimately whether
19 the warning letter should be admissible and whether the charge
10:24:57 20 should be given. I think those all can be taken up at trial.

21 THE COURT: All right. Then on those two issues,
22 we'll simply indicate in the minute entry that the approach to
23 the FDA warning letter in this trial is the same as in Booker,
24 that that's an issue that shouldn't be raised in front of the
10:25:12 25 jury without first being raised with me. But I'll consider it

10:25:16 1 in the same manner we did based on what's been presented and
2 argued to the jury. And I will consider the FDA instructions
3 at the time we settle jury instructions.

4 On that point, my intention on jury instructions is
10:25:30 5 to look at what you propose in your final pretrial order for
6 revisions to the jury instructions and then revise them and
7 get them back to you during the first week in trial so we can
8 then set a time to talk about them.

9 There's some obvious changes. I mean, we're not
10:25:45 10 going to have the same nonparty at fault doctors or
11 intervening cause claims. There may be others that are made.
12 But there's some changes that need to be made. The basic
13 claims are the same. Although I understand from what my
14 judicial assistant said this morning that you are dropping
10:26:09 15 Mr. Jones' loss of consortium claim?

16 MR. O'CONNOR: That's correct.

17 THE COURT: Okay. I was thinking we'd have to add an
18 instruction on that, but we won't.

19 Okay. So look over the instructions. Comment on
10:26:21 20 what you think should be changed and I'll turn them around and
21 get them back to you during the first week of trial and we can
22 talk about them then, along with the FDA proposal that the
23 plaintiff's making.

24 Did you guys hear that?

10:26:34 25 MR. STOLLER: I'm sorry, Your Honor.

10:26:35 1 THE COURT: I didn't think you did.

2 You can read the transcript on that.

3 No.

4 I'll get you the instructions during the first week
10:26:43 5 of trial and you can make your FDA instruction proposal then.

6 I will tell you that as I read it again, it still
7 seems to me to be like a pretty direct comment on the
8 evidence. So you might think about whether there's a way to
9 rephrase it to make clear the point that the FDA 510(k)
10 process decides substantial equivalence and does not address
11 the same thing as the PMA process which decides fair -- I mean
12 safety and effectiveness. It may be more persuasive to me if
13 it's reworded a bit. But that's up to you as to whether or
14 not you want to do that. I'm happy to hear whatever you
10:27:08 15 propose.

16 I think that addresses all of the issues that were
17 raised in the briefs for today.

18 There's another issue that the defendants raised,
19 which is the redaction of matters from the Booker trial. But
10:27:46 20 before we address that, is there anything else you all want to
21 raise in the nature of changes in rulings with respect to
22 Jones that hasn't been discussed?

23 MR. ROGERS: Nothing from the defendant, Your Honor.

24 MR. O'CONNOR: Nothing from us, the plaintiffs.

10:28:05 25 THE COURT: On this redaction issue, help me

10:28:07 1 understand what it is -- by the way, I don't have any problem
2 with waiting until all the transcripts are in to make the
3 decision, but I'm not clear in what we would be redacting and
4 why.

10:28:21 5 MS. HELM: Thank you, Your Honor.

6 In previous litigation, the plaintiffs took the
7 position that exhibits tendered into evidence during the trial
8 were now public and had to be sealed. And we addressed
9 that --

10:28:33 10 THE COURT: Had to be sealed?

11 MS. HELM: We had to move to seal them because they
12 became public records once they were tendered as exhibits at
13 trial.

14 So there are limited number -- I understand the
10:28:46 15 exhibits have been given back to the parties. I guess the
16 electronic version still exists here in the court. But --

17 THE COURT: But it's not in the docket.

18 MS. HELM: Correct.

19 THE COURT: And might have even been wiped off the
10:29:00 20 computer. Traci is nodding. I think it's been eliminated
21 from the computer that was in the jury room. So I don't think
22 we have the exhibits here any more.

23 MS. HELM: Okay. So I guess the clarification is to
24 the extent that the plaintiffs take the position that because
10:29:14 25 an exhibit was tendered into evidence at trial, in order to

10:29:19 1 protect that from being disseminated publicly outside of the
2 confines of the trial, do we need to move to seal them?
3 Because if we don't, then a substantial portion of the
4 potential motion is not necessary. If we do, then there are a
10:29:39 5 limited number of exhibits we would move to seal.

6 And we understand the sealing standard and all of
7 that.

8 But we raise this issue -- I raised it at the
9 pretrial and we're raising it because of a position they took
10:29:51 10 in a case, the case in Nevada a few years ago.

11 THE COURT: Let me make sure I understand what you're
12 saying, Ms. Helm. You said if they don't. If they don't
13 think it needs to be sealed, you're okay. Are you thinking
14 it's then governed by the protective order in terms of use in
10:30:07 15 other places?

16 MS. HELM: Yes, Your Honor.

17 THE COURT: Okay. I'll be happy to hear from
18 plaintiffs on that.

19 As you know, because we're at the dispositive portion
10:30:16 20 of the trial, the Ninth Circuit standard is compelling need or
21 compelling interests.

22 MS. HELM: Your Honor, I'm well aware of the
23 standard. And then I don't -- there may be very, very limited
24 portions of the transcript where an exhibit is read in detail
10:30:36 25 that we might seek to redact. Frankly, I'm going through it

10:30:41 1 as quickly as I can and haven't gotten to anything yet, but I
2 just want to make sure that we have that -- that we preserve
3 that right. And ask that we do it -- the whole purpose was
4 let's just do it one time rather than having to do it every
10:30:58 5 time a transcript drops.

6 THE COURT: Okay. Thank you.

7 MS. HELM: Thank you.

8 THE COURT: Plaintiff's counsel.

9 MR. O'CONNOR: Your Honor, the people on our team
10:31:08 10 that are working on this are not here. But as a practical
11 matter, this courtroom is open to the public, and so anything
12 that comes into evidence is a matter of public record.

13 And to the extent that this should probably be
14 briefed, I think that's what we think should happen here
10:31:26 15 because it's been a major issue, and I think it's going to
16 continue to be an issue in these trials, as to what they
17 contend should not be a matter of public record, or whatever
18 their position is.

19 THE COURT: Okay. I understand that.

10:31:44 20 You do need to file a motion in light of the
21 plaintiff's position. And I agree that we should only do it
22 once. So is your thought that within a certain number of days
23 after the last transcript is produced?

24 MS. HELM: Following the order or rule, my proposal
10:31:57 25 is 21 days after the last transcript drops.

10:31:59 1 THE COURT: When you say drops, you mean gets in the
2 docket?

3 MS. HELM: Yes, sir.

4 THE COURT: Any objection to that?

10:32:08 5 MR. O'CONNOR: The timing of where that may end up in
6 our trial -- and I believe Julia Zaic and Laura Smith are the
7 two people that are front and center on this, I believe.

8 I believe for the time that makes sense.

9 THE COURT: What I will do is say in the minute entry
10:32:28 10 that 21 days after the last transcript is filed in the docket,
11 the motion will be filed. And it will be briefed in the
12 normal course. If you find that because we're in the Jones
13 trial at that time you need an extension, you can raise that
14 with me, obviously.

10:32:42 15 Question. How do you know when it's the last
16 transcript?

17 Are you keeping track?

18 MS. HELM: We're following it. We're following it,
19 Your Honor.

10:32:55 20 THE COURT: Okay. We'll trust you to correctly
21 identify it.

22 MS. HELM: And once we identify -- once we think the
23 last transcript has been filed on the docket, we'll notify the
24 plaintiffs and we can file something with the Court if you
10:33:06 25 want, just to file a notice that will start the briefing.

10:33:11 1 THE COURT: Okay. Hold on.

2 (The Court and the court reporter confer.)

3 THE COURT: Ms. Helm, I assume the transcripts we're
4 talking about are just trial transcripts; right?

10:35:33 5 MS. HELM: Yes, Your Honor.

6 THE COURT: Not any other hearing transcripts?

7 MS. HELM: No, no, just trial transcripts. And I
8 actually -- I think it actually may have -- we may be 21 days
9 from yesterday.

10:35:41 10 THE COURT: Tricia tells me that she has finished the
11 transcripts for the verdict return and that's going to be
12 filed. She was going to confirm with Elaine that everything
13 Elaine has done is on the docket.

14 But assuming the verdict is the last one, she'll say
10:35:56 15 on the docket last trial transcript, and that will trigger the
16 21 days.

17 MS. HELM: Yes, Your Honor.

18 THE COURT: Now, something she pointed out that I
19 don't think is a problem, is that under the local rules
10:36:07 20 there's 90 days to seek redaction of a transcript. After 90
21 days the transcript is made available to the public.

22 I'm assuming that 21 days after today or tomorrow --
23 or Monday will not be 90 days after the first trial transcript
24 was filed. I think we're okay within that window.

10:36:28 25 MS. HELM: I think if -- 21 days from today, for

10:36:33 1 example, is going to be May 4th and we started trial on
2 March 13, so we're within the 90.

3 THE COURT: Okay. So we should be okay on that.

4 MS. HELM: April, May, June. As long as we have it
10:36:48 5 done by whatever the June date is.

6 THE COURT: Okay. So you don't need to file
7 anything, Tricia will simply note it's the last transcript and
8 that will be the trigger.

9 MS. HELM: That will be our trigger.

10:37:10 10 THE COURT: Okay. In terms of the schedule that
11 remains, as you know -- I will tell you we have the jury
12 questionnaires in. I have not -- we don't necessarily have
13 all of them, but we've got a big stack. I've not gone through
14 them yet to identify who is going to be excused for hardship.

10:37:35 15 The questionnaires will be again available for you to
16 pick up on the 20th of this month. On the 24th, I will tell
17 you who is being excused for hardship. And then on May 4th we
18 will talk about those jury issues, as we did at the last final
19 pretrial conference.

10:38:01 20 In terms of the other dates that are relevant, we
21 said in the order that was entered at Docket 10587 that the
22 final pretrial order is due on April 27th.

23 Motions in limine are due on April 18th.

24 Responses to motions in limine on April 25th.

10:38:27 25 And, again, it's still -- there's a page limit that's

10:38:30 1 identified in the order.

2 And deposition designations by April 20th.

3 And then we're going to have the final pretrial
4 conference, as indicated, on May 4th.

10:38:59 5 That's everything that I had on my list. Do
6 plaintiffs have other matters you'd like to raise?

7 MR. O'CONNOR: Yes, Your Honor.

8 We are in the process today, I think, of exchanging
9 exhibits. And while we have that long exhibit list from the
10:39:14 10 Booker trial, we're in the process of identifying as best we
11 can a set of exhibits that we believe will be used in this
12 trial.

13 What we would like is a meaningful meet and confer
14 with the defendants about admissibility of exhibits that we
10:39:36 15 will be able to provide them. And if that doesn't work,
16 discussion about a procedure where we could sort some of those
17 evidentiary foundational issues out before we come down here
18 and use our time on that.

19 I think under Rule 104(a), that gives us some -- at
10:39:59 20 least some authority we should be able to, if necessary, call
21 a custodian of records, get a Rule 30(b)(6) witness, and try
22 to address a lot of these issues before we ever step in this
23 court for trial and our time on the clock starts ticking away.

24 So we are taking steps to work on that on our end,
10:40:18 25 but we would like to have a lot of this worked out before we

10:40:22 1 get to trial so we know what will be coming in for sure and
2 what will not.

3 THE COURT: So what precisely are you proposing,
4 Mr. O'Connor?

10:40:32 5 MR. O'CONNOR: Right now Mr. Combs is working on
6 exhibits. I think, first of all, we should have set up a time
7 to meet with the defense and quickly find out what objections
8 they have and who is available on the defense side that we
9 could depose outside of the court, for example, to get the
10:40:50 10 evidentiary deficiencies they claim exist out of the way, and
11 present it that way. Under maybe perhaps a Rule 104 procedure
12 in advance of court to deal with admissibility of evidence.

13 And I can give you examples of things. You know, we
14 went through the whole thing about the monthly reports that
10:41:14 15 finally came in --

16 THE COURT: I know your examples.

17 MR. O'CONNOR: Pardon me?

18 THE COURT: I know your examples. I know the issues
19 that came up about the documents.

10:41:21 20 What are defendants' thoughts on this?

21 MS. HELM: Your Honor, I have told Mr. Stoller on
22 more than one occasion that we will be happy to sit down and
23 meet and confer and go over the exhibits and stipulate to as
24 many as we possibly can.

10:41:36 25 One issue that continues to come up is I don't think,

10:41:39 1 and I stand corrected if I did, that we ever made them prove
2 up, or if we did, we are not going to, a document as a
3 regularly kept business record of Bard. We'll stipulate the
4 documents are regularly kept business records of Bard.

10:41:55 5 But there are other objections that may apply to an
6 exhibit, depending on who's the witness with whom they try to
7 use it, or there may be, as we -- as we learned in Booker,
8 hearsay-within-hearsay issues. Some of those are resolved
9 because you ruled on them and we have redacted documents.

10:42:14 10 But we're happy to talk about and to stipulate that
11 exhibits are regularly kept business records, but we can't
12 stipulate that they're admissible for all reasons because
13 there may be foundation issues and there may be other issues.
14 But we've always said we would have a meaningful meet and
10:42:32 15 confer with them.

16 THE COURT: Mr. O'Connor.

17 MR. O'CONNOR: I think we're happy to set anything.
18 Not that I'm a pessimist, but I do think eventually we're
19 going to have to discuss a procedure to -- to address
10:42:52 20 foundational issues that we may not be able to agree to.

21 And, you know, in terms of how the exhibits are used
22 once we get all the foundational requirements and evidentiary
23 requirements, I suppose those are issues we'll deal with in
24 trial. But as much as we can get that ironed out and make the
10:43:10 25 time that you're allotting us used for putting in evidence and

10:43:14 1 proving it to this jury, is, I think, to everybody's advantage
2 in this court.

3 THE COURT: Well, Ms. Helm just said they would be
4 willing to stipulate to business records for Bard documents.
10:43:29 5 That, to me, is the biggest issue you were encountering on
6 some of those exhibits. So work through those.

7 MR. O'CONNOR: We'll work through that.

8 THE COURT: If there are other issues --
9 admissibility issues, hearsay within hearsay, personal
10:43:43 10 knowledge of the witness, some of the other objections that
11 were made -- they can preserve those for trial. And those
12 aren't the kinds of objections that are likely to be resolved
13 in a 104(a) hearing. If it's hearsay within hearsay, it is.

14 MR. COMBS: Your Honor, I just wanted to interject --

10:44:01 15 MR. O'CONNOR: Lincoln Combs.

16 MR. COMBS: Yeah, Lincoln Combs for the plaintiffs,
17 Your Honor.

18 We've got -- the list we sent this morning is about
19 265 I'm told of what we think will be the focus of Jones.
10:44:15 20 We're still reserving the right to go to the bigger of about
21 4400 that was the Booker list. But that 265 includes a lot of
22 those. It's about half new and about half stuff from Booker.
23 So our hope is that with a much more manageable list, we can
24 go through them, document by document if we have to, in that
10:44:36 25 kind of process.

10:44:37 1 And as you probably remember, I have done that with
2 Ms. Helm before for privilege logs. We've gotten granular
3 when we've had to to get bigger picture rulings from you. So
4 we can certainly do that kind of process.

10:44:50 5 THE COURT: Well, yeah, that's what you ought to do.
6 I agree. You should. Good idea.

7 MR. O'CONNOR: We just need to set it up and make
8 sure it happens.

9 THE COURT: Well, you're all here. You've got your
10 calendars. Set it up before you leave.

11 MR. O'CONNOR: We can do that now.

12 THE COURT: You don't need to do it on the record.

13 Any other matters from the plaintiffs?

14 MR. CLARK: Your Honor, Shannon Clark.

10:45:11 15 Just one housekeeping matter. I was curious if the
16 Court still had a Word version of the final preliminary
17 instructions that were given to the jury and the final
18 instructions that were given to the jury on March 29th?

19 THE COURT: Yes, we do.

10:45:25 20 MR. CLARK: Going through there, I thought that would
21 be a good template to work from, and it would be much easier
22 if it was in a Word document.

23 MS. HELM: That would be very helpful.

24 THE COURT: We can e-mail it to you. I'll have Nancy
10:45:34 25 e-mail to you the preliminary instructions we gave at the

10:45:36 1 beginning of the case and the final instructions and you can
2 then work off that document.

3 MR. CLARK: Thank you, Your Honor.

4 MS. HELM: That would be very helpful, Your Honor.

10:45:43 5 Thank you.

6 THE COURT: Anything from defendants?

7 MS. HELM: Yes, Your Honor.

8 The plaintiffs have asked us to accept subpoenas for,
9 and my number is going to be approximate, somewhere between
10:45:55 10 approximately 14 or 15 either Bard employees or former
11 employees, and we've agreed to do that. We also agreed to do
12 that in Booker, and there were 15 or 16 Booker and they
13 actually ended up only calling four of those people. We had
14 one witness who sat in the courthouse all day and never got
10:46:17 15 called.

16 We'd just ask by the time of the pretrial conference
17 if plaintiffs could let us know whether they can narrow that
18 list down or when they actually need people, because we're
19 asking these folks to put their personal and professional
10:46:34 20 lives on hold for two weeks. Also, it's during May, which is
21 a busy season for anyone who has school-aged children and
22 people are trying to plan vacations and graduations and things
23 like that. So we would ask for a little more direction on the
24 schedules for these 14 people. And if they're not going to
10:46:57 25 use them, if they would let us know. Not asking for it today,

1 just asking that that be addressed at the time of the pretrial
2 conference.

3 THE COURT: I think that's reasonable. I think you
4 all can talk about that.

5 Anything else we need to address?

6 All right.

7 MR. O'CONNOR: Nothing from the plaintiffs. Thank
8 you.

9 MR. ROGERS: Nothing from the defendants.

10 THE COURT: See you on May 4th. Thanks.

11 MR. ROGERS: Thank you.

12 MR. STOLLER: Thank you, Your Honor.

13 (End of transcript.)

14 * * * * *

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 20th day of April, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter